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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,455	01/27/2004	Hiroyuki Ebinuma	248076US0	8679
22850	7590	06/22/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			GITOMER, RALPH J	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/764,455

Applicant(s)

EBINUMA ET AL.

Examiner

Ralph Gitomer

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election with traverse of Group II, claims 6-10, in the reply filed on 4/24/06 is acknowledged. The traversal is on the ground(s) that the reagents of Group II must be used in the method of Group I. This is not found persuasive because the reagents and methods are distinct inventions. Further, no novel compounds are found in the reagent claims so rejoinder is not proper.

The requirement is still deemed proper and is therefore made FINAL.

The claims are directed to a reagent composition containing a dehydrogenase, albumin, NAD, and a tetrazolium. Although not claimed, the specification as originally filed describes the function of the albumin as a component to reduce interference of hemoglobin in dehydrogenase based assays.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-10 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Moyer and Kuniaki.

Moyer (3,791,933) entitled "Rapid Methods for Assay of Enzyme Substrates and Metabolites" teaches in claim 1 a device for quantitating metabolites in body fluids such as blood, urine, cerebrospinal fluid and the like. In claim 8 the device contains the reagents of human serum albumin, NAD, dehydrogenase, N-methyl phenazonium methosulfate, and nitro blue tetrazolium.

Kuniaki (60-66993) entitled "Method For Measuring Components in Body Fluids", English translation provided, teaches reducing interferences in dehydrogenase reactions. In the English translation, on page 14 a reagent composition is shown containing dehydrogenase, bovine albumin, NAD. On pages 25-26 a reagent is shown containing dehydrogenase, NADP⁺, bovine albumin. Various tetrazolium salts are shown throughout the article for redox color determinations, see page 7 last paragraph.

Claims 6-10 are rejected under 35 U.S.C. 102(a) as being anticipated by each of Parsons and Ghoshal.

Parsons (6,703,216) entitled "Methods, Compositions and Apparatuses for Detection of GHB" teaches in column 4 last full paragraph, a dehydrogenase reacts with NAD⁺ to produce an aldehyde and NADH where the NADH is reacted in a second reaction to form a colored product. In column 14 line 50, the assay can include albumin. In column 15 line 23, bovine serum albumin specifically is shown. In column 15 lines 50-56, hemoglobin suppressors can be used to decrease the nonenzymatic dye forming

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reaction between hemoglobin and a tetrazolium compound for those samples containing hemoglobin or other heme containing groups. In column 24 line 34 NAD is shown. In column 27 lines 15+ various tetrazolium salts are taught.

Ghoshal (6,811,998) entitled "Conjugates of Uncompetitive Inhibitors of Inosine Monophosphate Dehydrogenase" teaches in column 1 lines 26-37, a dehydrogenase reaction sequence with NAD which forms NADH. In column 6 first paragraph the NADH is measured with a tetrazolium salts with phenazine methosulfate as an electron carrier. In column 6 line 23 albumin may be included.

All of the features of the reagent claims are taught by each of the above references.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 6, line 3, which refers to an enzyme's ability, as compounds do not have abilities the enzyme may be better defined as a dehydrogenase.

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The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer
Primary Examiner
Art Unit 1655

RALPH GITOMER
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